510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

SAMSUNG MEDISON CO., LTD.
42, Teheran-ro 108-gil, Gangnam-gu,
Seoul, Korea

Contact Person:
Kyeong-Mi, Park
Regulatory Affairs Manager

Telephone: 82.2.2194.1373
Facsimile: 82.2.556.3974

OCT 04 2013

Data Prepared: July31, 2013

2. Name of the device:

Common/Usual Name:
Diagnostic Ultrasound System and Accessories
Proprietary Name:
UGEO H60 Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

3. Identification of the predicate or legally marketed device:

- UGEO G60 Diagnostic Ultrasound System(K122583)
- UGEO HM70A Diagnostic Ultrasound System(K130803)

※ The proprietary name of predicate device (K122583) was changed to UGEO H60 Diagnostic Ultrasound System from UGEO G60 Diagnostic Ultrasound System.

4. Device Description:

The UGEO H60 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging(including Directional Power Doppler mode; S-Flow), PW/CWSpectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, 3D imaging mode (real time 4D imaging mode) or as a combination of these modes. The UGEO H60 also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The UGEO H60 has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

5. Intended Uses:

The UGEO H60 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Pediatric, Small Organs, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial),Cardiac Adult, Cardiac Pediatric and Peripheral vessel.

6. Technological Characteristics:

The UGEO H60is substantially equivalent with respect to safety, effectiveness, and functionality to the UGEO H60 Diagnostic Ultrasound System (K122583) and UGEO HM70A Diagnostic Ultrasound System (K130803).
It is substantially equivalent with respect to safety, effectiveness, and functionality to the Bodymarker of UGEO H60 (K122583) and UGEO HM70A (K130803) in regards to the device with e-Motion Marker.
All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.
These are described in detail in the technological characteristics comparison table as below.

<Technological Characteristics Comparison Table>

Feature / Characteristics	The subject device	The predicate devices	
	UGEO H60	UGEO H60 (K122583)	UGEO HM70A (K130803)
Indication for Use			
- Fetal	√	√	√
- Abdominal	√	√	√
- Pediatric	√	√	√
- Small Organ	√	√	√
- Neonatal Cephalic	√	√	√
- Adult Cephalic	√		√
- Trans-rectal	√	√	√
- Trans-vaginal	√	√	√

Feature / Characteristics	The subject device	The predicate devices	
	UGEO H60	UGEO H60 (K122583)	UGEO HM70A (K130803)
- Musculo-skeletal (Conventional)	√	√	√
- Musculo-skeletal (Superficial)	√	√	√
- Cardiac Adult	√		√
- Cardiac Pediatric	√		√
- Peripheral vessel	√	√	√
Scanhead Types			
- Linear Array	√	√	√
- Curved Linear Array	√	√	√
- Endocavity	√	√	√
- Phased Array	√		√
- Static Probes	√		√
Scanhead Frequency			
1.0 ~ 20.0 MHz	√	√	√
Modes of Operation			
- B-mode	√	√	√
- M-mode	√	√	√
- Pulsed wave (PW) Doppler	√	√	√
- Continuous wave (CW) Doppler	√		√
- Color Doppler	√	√	√
- Power Amplitude Doppler	√	√	√
- Tissue Harmonic Imaging	√	√	√
- 3D/4D imaging mode	√	√	√
- Combined modes	√	√	√
Safety & EMC Compliance			
- IEC60601-1 - UL 60601-1 - CSA C22.2 No.601.1	√	√	√
- IEC 60601-2-37	√	√	√
- IEC 60601-1-2	√	√	√
Acoustic Output Display Standard			
Track 3	√	√	√
Patient Contact Materials			
Tested to ISO 10993-1	√	√	√
Functionality			
- Quick Scan (Q Scan)	√	√	√
- Spatial Compound Imaging	√	√	√
- SMDR (Dynamic MR Plus)	√	√	√
- Auto IMT	√		√
- 3D Imaging (Volume Data Acquisition)	√	√	√
- 3D Imaging presentation (3D Cine/4D Cine)	√	√	√
- 3D Rendering MPR(Multi Planer Render)	√	√	√
- 3D XI MSV(Multi Slice View) Oblique View	√	√	√
- 3D MagiCut	√	√	√

Feature / Characteristics	The subject device	The predicate devices	
	UGEO H60	UGEO H60 (K122583)	UGEO HM70A (K130803)
- Volume Calculation (VOCAL)	√	√	√
- Volume NT/IT	√	√	√
- e-Motion Marker	√	√[1]	√[1]

1) BodyMarker

7. A brief discussion of the bench and non-clinical tests conducted on the subject device

The device has been evaluated for acoustic output, biocompatibility effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform to applicable medical device safety standards.

The UGEO H60 and its application comply with voluntary standards as below:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1,Safety requirements for Medical Equipment
- EN/IEC60601-1-2,EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO10993-1, Biocompatibility
- ISO14971, Application of risk management to medical devices

Summary of Clinical Tests:

Not applicable. The subject of this submission, UGEO H60, did not require clinical studies to support substantial equivalence.

8. Conclusion

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the UGEO H60to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

END of 510(K) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

Samsung Medison Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Service LLC.
1394 25th Street NW
BUFFALO MN 55313

Re: K132861
Trade/Device Name: UGEO H60 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 11, 2013
Received: September 12, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the UGEO H60 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

CS1-4	C2-8	CF4-9	ER4-9	EVN4-9
L5-13	3D2-6	VE4-8	3D4-9	CF2-8
LF5-13	PE2-4	SP3-8	CW2.0	CW4.0

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

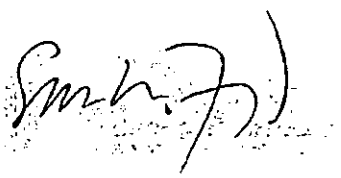
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and.listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shing Chun Benny Lam, Ph.D. at (301) 796-9328.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosures

INDICATIONS FOR USE

510(k) Number (if known): K132861

Device Name: UGEO H60 Diagnostic Ultrasound System

Indications for Use:

The UGEO H60 Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.
The clinical applications include: Fetal, Abdominal, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult, Cardiac Pediatric and Peripheral vessel

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132861

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name:UGEO H60Diagnostic Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 4, 7, 8
	Abdominal *(See Note 10)*	P	P	P	N	P	Note 1	Notes 2, 4, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	N	P	Note 1	Note 2, 4, 5, 6, 7, 8, 9
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 6, 7, 8, 9
	Neonatal Cephalic	P	P	P		P	Note 1	Note 2, 7, 8
	Adult Cephalic	N	N	N	N	N	Note 1	Notes 4, 7
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Notes 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Notes 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	N	P	Note 1	Note 2, 5, 6, 7, 8, 9
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW,Dual/Quad (B, B+C, B+PD,B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: CS1-4 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal*(See Note 10)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: C2-8 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal*(See Note 10)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared byFDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: CF4-9 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal*(See Note 10)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 2, 7, 8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 2, 7, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: ER4-9 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal*(See Note 10)*							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: EVN4-9 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track 1 only)	Specific (Tracks 1 & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal *(See Note 10)*							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Notes 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Notes 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: L5-13 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal*(See Note 10)*							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: 3D2-6 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal*(See Note 10)*	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: VE4-8 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal *(See Note 10)*	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: 3D4-9 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal *(See Note 10)*							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K122583; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: CF2-8 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N		N	Note 1	Notes 2, 4, 7, 8
	Abdominal*(See Note 10)*	N	N	N		N	Note 1	Notes 2, 4, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Notes 2, 4, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared byFDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: LF5-13 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal*(See Note 10)*							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2, 5, 6, 7, 9
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: PE2-4 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks 1 & III)	B	M	PWD	CWD	, Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: SP3-8 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal	N	N	N	N	N	Note 1	Note 4, 7
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD+PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: CW2.0 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
Device Name: CW4.0 for use with UGEO H60
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track 1 only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric				P			
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K130803; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B+M, B+PW, B+CW, B+C, B+PD, B+DPD, B+C+PW, B+PD+PW, B+DPD+PW, B+TD/PW, B+C+M, B+C+CW, Dual/Quad (B, B+C, B+PD, B+TD, B+DPD)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Spatial Compound Imaging
Note 10: Includes Renal, Gynecology/Pelvis

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)